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EC Communication Defines Principles on Limiting Most Harmful Chemicals to Essential Uses

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On April 22, 2024, the European Commission (EC) announced that it adopted a "Communication from the Commission: Guiding criteria and principles for the essential use concept in EU legislation dealing with chemicals." The press release states that "[t]he overall aim of this concept is to achieve higher regulatory efficiency and predictability for authorities, investors and industry for a faster phase-out of the most harmful substances in non-essential uses, while allowing more time for the phase-out of uses that are essential for society." The EC intends the concept also to help industry to prioritize investments in innovative and sustainable chemicals in the European Union (EU).

Criteria for Essential Use

The Communication states that a use of a most harmful substance is essential for society if the following two criteria are met:

- That use is necessary for health or safety or is critical for the functioning of society; and
- There are no acceptable alternatives.

The Communication aims to provide clarity on these criteria and on how they can be implemented in legislation. The EC states that it "does not intend to change existing references to a technical and/or economic feasibility assessment if it proposes to introduce the essential use concept in any such legislative area." The EC will weigh the appropriateness of such references to the legislative context when considering the introduction of the concept of essential use in any other areas.

Terms Underpinning the Essential Use Concept

The Communication defines the following terms for the essential use concept:

- Most harmful substances: A most harmful substance has one or more of the following hazard properties:
    - Carcinogenicity Category (Cat.) 1A and 1B;
    - Germ cell mutagenicity Cat. 1A and 1B;

- Reproductive/developmental toxicity Cat. 1A and 1B;
- Endocrine disruption Cat. 1 (human health);
- Endocrine disruption Cat. 1 (environment);
- Respiratory sensitization Cat. 1;
- Specific target organ toxicity — repeated exposure (STOT-RE) Cat. 1, including immunotoxicity and neurotoxicity;
- Persistent, bioaccumulative, and toxic/very persistent and very bioaccumulative (PBT/vPvB);
- Persistent, mobile, and toxic/very persistent and very mobile (PMT/vPvM); and
- Hazardous to the ozone layer Cat. 1.

- Necessary for health or safety: The use of a most harmful substance is necessary for health or safety if the use and the technical function of the substance in that use are necessary to:
  - Prevent, monitor, or treat illness and similar health conditions;
  - Sustain basic conditions for human or animal life and health;
  - Manage health crises and emergencies;
  - Ensure personal safety; or
  - Ensure public safety.

- Critical for the functioning of society: The use of a most harmful substance is critical for the functioning of society if the use and the technical function of the substance in that use are critical to:

- Provide resources or services that must remain in service for society to function (*e.g.*, ensure the supply of energy and critical raw materials or resilience to supply disruption);
- Manage societal risks and impacts from natural crises and disasters;
- Protect and restore the natural environment;
- Perform scientific research and development; or
- Protect cultural heritage.

- Acceptable alternatives: Acceptable alternatives are substances, materials, technologies, processes, or products that, from a societal point of view:
  - Are capable of providing the function and the level of performance that society can accept as sufficiently delivering the expected service; and
  - Are safer (their overall chemical risks to human or animal health and the environment throughout the whole life cycle are lower in comparison to the most harmful substance).

  The Communication notes that acceptability of alternatives takes a societal perspective. According to the Communication, the notion of an “acceptable alternative” is usually defined with specific requirements in each piece of legislation, and for most pieces of legislation also includes a technical and/or economic feasibility assessment. The Communication states that these existing definitions (for example, technical and/or economic feasibility) should be considered if and when implementing the essential use concept in such areas.

- Use of a substance: Any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article, or any other utilization.
- Technical function of a substance (in the use): The role that the substance fulfills when it is used, *i.e.*, what it does in a process, mixture, or article. The Communication states that technical functions are, for example, extraction solvent, degreasing agent, or corrosion inhibitor.
- Final product: A product (substance on its own, a mixture, an article, or a complex product) used by consumers or industrial or professional users. A most harmful substance can be used to produce the final product (while not being present in the final product itself) and/or it can be contained in the final product.

- Service: The purpose(s) that the final product fulfills for its user or receiver (an activity or function, not a physical object).

Principles of the Essential Use Concept

The Communication states that the core principles of the essential use concept are as follows (emphasis in the original):

- The aim of the concept is to increase the protection of health and environment by **accelerating the phase-out of the uses of the most harmful substance that are non-essential and, where they are essential, to provide time for their substitution**.
- The concept is intended to **determine** whether it is **essential for society** to use a most harmful substance with **a certain technical function**, with that substance either present in a final product or used to produce that product or provide a service. In all cases, it will be necessary to **take into account the context of the use** provided by the final product and the service or purpose that it fulfills for society and the users (*e.g.*, consumers). The use of a substance may be critical for the functioning of society or necessary for health or safety in one context but not in another (*e.g.*, the need to use the substance providing a certain technical function in a lamp for surgery at a hospital may be different from the need to use it for a lamp at home or in a shop).
- The concept is **not intended to determine whether a certain substance, product, product group, or service is *itself* essential for society, nor whether an individual consumer or company considers the use essential for them**.

- An **assessment of the use** and its context is needed. Specific uses of a most harmful substance within any sector could either fulfill the first criterion or not (*e.g.*, use of a substance in an airplane engine providing a technical function necessary for safety vs. in an airplane seat or carpet with a technical function purely for decoration).

- **For a use to be proven essential, both criteria must be met. To simplify and increase efficiency** of the assessment, if appropriate, uses under assessment may sometimes encompass broader product categories, and the assessment of criteria may be done in a structured manner (one by one).

- For uses proven essential, **conditions** should usually be set to **minimize** the **emissions and the exposure** of humans and the environment, in particular to avoid or minimize exposure of vulnerable groups such as children, pregnant women, and elderly people, who are more sensitive to exposure of harmful chemicals.

- **The essentiality of a use is not static**, but evolves over time, in function of new information on hazards, new societal challenges and needs, and new, innovative alternatives emerging. In balance between reasonable investment horizons, incentives to innovate in safer alternatives by way of prospects of later market penetration and the general aim of minimizing use of most harmful substances, notably in consumer products, it is in most cases useful to set a time limit and review essential use permits at the appropriate moment.

- To take account of this evolutionary nature of essential uses, **substitution plans with commitments, timelines, and steps envisaged toward transition to alternatives** could be required for uses of substances that are deemed essential, and possible inclusion into research and innovation agendas could also be considered.

Questions and Answers (Q&A)

The EC posted Q&As on essential use chemicals. The Q&As state that "[t]he essential use concept is about specific uses of certain chemicals. The use of a substance may be essential in one product or context, but not in another. In addition, not all uses may be essential within a sector." According to the Q&As, the Communication will benefit companies "by providing predictability in terms of types of chemical substances and uses which shall be targeted for phase-out by future regulatory processes, and which ones may continue to be used to fulfil societal needs, provided there are no alternatives available." The Q&As include the following:

> How will the Communication on essential use interact with ongoing legislative initiatives such as the [Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)] restriction of [per- and polyfluoroalkyl substances (PFAS)], the revision of REACH, and any other legislative revisions?
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> The Communication sets out the guiding principles and criteria for the essential use concept. It defines the guiding principles and criteria for incorporating the concept in EU legislation in a harmonised way and clarifies that, when incorporating the concept into EU legislation, the specificities of the legislation and of the regulated area must be carefully considered. The essential use concept has only legal effect once included in legislation. This would happen based on an impact assessment.
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> Currently, the concept is not part of the REACH regulation, and hence not of current initiatives like the PFAS restriction. However, the Communication reiterates and further clarifies that the Commission is committed to phasing out the most harmful substances, while at the same time still allowing for their use where proven essential for society, and in particular for ensuring the green and digital transition.

Commentary

The concept of essential use is one of the core chemical management frameworks. Certain chemical uses are critically important, and regulatory bodies globally understand this. The Communication lays out a sensible regulatory construct that seems to include the relevant factors and consideration that help shape a practical approach to defining essentiality in the chemical use context. The Communication will undoubtedly be a starting point for other regulatory frameworks globally. Chemical stakeholders are urged to review it.

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